

## REMARKS

With entry of this amendment, claims 1, 4-6, 9-16, 18, 19, 21-23, 26-42 and 59-69 are pending in the application. Claims 2 and 25 are canceled without prejudice. Claims 1, 9, 10, 18, 26, 27 and 59 are currently amended. The amendments do not present new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

### I. Withdrawn Rejections

Applicant acknowledges that the following rejections set forth in the final Office Action mailed August 1, 2008 were withdrawn:

- A. Rejection of claims 2, 14 and 15 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Publication No. 2003/0098271 A1 to Somack *et al.* (hereafter “Somack”).
- B. All rejections of claims under 35 U.S.C. §103(a) involving U.S. Publication No. 2004/0126281 to Morrison (hereafter “Morrison”) including the rejection of claims as allegedly being unpatentable over Somack in view of Morrison, the rejection of claims as allegedly being unpatentable over Somack in view of Morrison and further in view of U.S. Patent No. 5,219,294 to Marsh *et al.* (hereafter “Marsh”), the rejection of claims as allegedly being unpatentable over Morrison in view of U.S. Patent No. 6,770,487 to Crosby (hereafter “Crosby”), the rejection of claims as allegedly being unpatentable over Somack in view of Morrison and further in view of U.S. Publication No. 2002/0045272 A1 to McDevitt *et al.* (hereafter “McDevitt”), and the rejection of claims as allegedly being unpatentable over Somack in view of Morrison and Marsh.

### II. Claims 1, 4, 11, 12 and 16 Are Novel Over Somack

Independent claim 1 and dependent claims 4, 11-12 and 16 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Somack. Applicant respectfully submits that the rejection is moot.

It is conceded that “Somack fails to disclose a data storage device that is positioned in a recess.” Office Action (p. 3).

Somack also fails to disclose “a tray defining a plurality of apertures for holding respective biological specimen filters ... and further defining a separate recess configured to

mate or interface with a component of the specimen processing system.” No such structure is disclosed by Somack.

Somack also fails to disclose a data storage device positioned within the recess and “wherein data related to the respective filters is stored in the data storage device” as recited in claim 1.

It is alleged in the Office Action with reference to para. 10 of Somack that the cited reference discloses a “sample tray 50” configured to be processed by a workstation. Office Action (p. 2). It is also alleged that Somack paras. 9 and 60 describe a tray comprising a bar code associated with each aperture for storing data related to the filter, such as the type of filter used to immobilize the sample and the test to be performed on the sample. Office Action (p. 2).

Beginning with paras. 9 and 10, the cited sections of Somack explain that the “devices” of the present invention can be bar-coded for identifying the type of membrane, type of pre-loaded agent, intended application, and/or for sample identification. References to such “devices” in para. 9 are references to biological sample purification devices 8, which have a tubular body, first and second ends, and a species-immobilizing filter that is secured within the tubular body. Somack (para. 6) (“biological specimen purification devices”; “each device...”); (para. 7) (“Each device further includes a removable cap...”); (para. 8) (“multiple device and array tray system”); paras. 11, 29 and 67 (describing capsular device 8 having a tubular body 10, ends 11 and 21, and an end cap 16. A filter 20 is located at the lower end 21 of the tubular body 10).

Thus, with regard to paras. 9 and 10, Somack refers to “different types of devices” as different purification devices or capsules 8 that can be bar-coded, *not a tray, not tray apertures used to hold specimen filters, and not the filters themselves*. Further, as described by Somack, the purification or capsules 8 are positioned within holes 32 of a tray 22 such that the devices 8 snap into the tray 22. Somack (para. 69). Based on the structure described in para. 9, there is no data storage device positioned within a separate recess (which is not for a filter) and that is configured to mate or interface with processing system component since Somack explains that the holes 32 are for the capsule devices 8.

Turning to para. 60 of Somack, and with further reference to para. 9, it is alleged these paragraphs of Somack disclose a tray comprising “a bar code associated with each aperture for storing data related to the filter, such as the type of filter used to immobilize the sample and the

test to be performed on the sample.” Office Action (pp. 2-3). Somack refers to bar-codes on capsules and bar-codes “*on the holding tray*.” Somack (para. 60, line 4). Bar-codes on the holding tray correspond to “capsule positions.” Somack (para. 60, lines 4-5). Accordingly, the cited sections of Somack fail to disclose a tray defining apertures for holding respective biological specimens and, in addition, a separate recess configured to mate or interface with a component of the specimen processing system and also fail to disclose “a data storage device positioned within the recess, wherein data related to the respective filters is stored in the data storage device.”

Moreover, it is generally alleged that a barcode on a holding tray stores data related to the filter such as the type of filter to be used to immobilize the sample and the test to be performed. However, the Office action has not cited any section of Somack or which part of paras. 9 and 60 actually describes a bar code on a tray that stores data identifying the type of filter. Further, the Office action has not cited any section of Somack and has not identified which part of paras. 9 and 60 that actually describes a bar code on a tray that stores data of the test to be performed on the sample. These deficiencies are consistent with the fact that Somack para. 60 actually explains that the barcode on the tray correspond to capsule positions. As is well understood, the position of a capsule 8 does not identify a type of filter, a test to be performed, a specimen that is compatible with the filter, whether the filter has expired, or processing step parameters involving the filter.

Further, Applicant notes that Somack does not discuss filters 54 of the “plate assembly 50” (Figs. 7-11) in the context of capsules 8 and paras. 9 and 60. Rather, Somack refers to a plate assembly 50 with reference to different figures. In fact, Somack does not even refer to a capsule 8 when discussing plate assembly 50, which is consistent with the fact that Fig. 7, which shows a plate assembly 50, does not show a capsule 8. Thus, the Office Action is referring to different components that are not even structurally arranged as alleged.

Additionally, with respect to the particular structure of the “plate assembly 50” (Figs. 7-11), Somack is understandably silent as to a data storage device positioned within a recess configured to mate or interface with a component of the specimen processing system and a data storage device positioned within the recess and storing data related to respective filters.

The Office Action has also failed to establish that the plate assembly 50 (alleged tray) is configured to mate or interface with a component of a specimen processing system. Somack

para. 10 explains that a tray may be capable of automation of robotic work stations, but the cited reference is otherwise silent as to how this would be done, and the Office Action has not established that it is necessarily the case that the plate assembly (which is shown in Fig. 7 as having solid side walls) is so configured.

In this regard, and with respect to other aspects of claim 1 that are not specifically disclosed by Somack, Applicant also notes that these deficiencies and different descriptions of components have not established that such elements of claim 1 are inherently disclosed by Somack. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

In view of these substantial differences and deficiencies, claim 1 is fundamentally different than the limited disclosure provided by Somack, and Applicant respectfully submits that independent claim 1 is novel over Somack. Dependent claims 4, 11, 12 and 16, which incorporate the same limitations as claim 1, are also believed novel over Somack for at least these same reasons.

With regard to claim 16, it is alleged “it is evident that each bar code comprises a unique registration number. Otherwise, the bar code reader would not be able to identify and distinguish each bar code.” Office Action (p. 3). By alleging that something is “evident” it must be alleged that it is inherent since it is not specifically disclosed. However, these general allegations cannot support the rejection. The Office Action fails to consider the fact that Somack para. 60 explains that the barcode on the tray correspond to *different capsule positions*, and a bar code reader would identify and distinguish these different capsule positions.

In addition to these deficiencies, the cited section of Somack does not even refer to a unique registration number and does not even refer to a unique registration number *of the data storage device*. Rather, the Office Action merely generally alleges that a capsule position barcode necessarily requires a unique registration number of the data storage device. The very limited disclosure of Somack and the very limited remarks provided by the Office Action fail to establish how claim 16 is anticipated by Somack, particularly considering that the Office Action has not established that barcodes that are used for a different purpose of identifying different locations necessarily disclose a data storage device having stored data comprising a unique registration number of the data storage device. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient).

Accordingly, Applicant respectfully requests that the rejection of claims 1, 4, 11, 12 and 16 under 35 U.S.C. §102(b) be withdrawn, particularly considering that the Office Action has not established that certain elements are necessarily or inherently disclosed by Somack.

### **III. Claims 9, 10, 59-65 and 67-69 Are Patentable Over Somack, Nova and Marsh**

Claims 9 and 10 (which depend from claim 1), independent claim 59, and claims 60-65 and 67-69 (which depend from claim 59) stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of U.S. Patent No. 5,219,294 to Nova *et al.* (hereafter “Nova”) and further in view of Marsh.

Marsh is cited for the limited purpose of allegedly disclosing a parallel port connector for a computer and printer, and it is alleged that it would have been obvious to modify Somack to have the connection as disclosed by Marsh to securely dock the tray with a work station. Nova is cited for the limited purpose of allegedly disclosing memory in the form of a barcode, RAM or programmable ROM. It is alleged that it would have been obvious to use RAM or ROM instead of a barcode so that information to and from a work station can be quickly updated.

Initially, deficiencies of Somack with regard to independent claim 1 are discussed in Section II. The remarks in Section II also demonstrate the deficiencies of Somack with respect to independent claim 59, which recites *inter alia* “the tray further defining a separate data communications port configured to mate or interface with a component of the specimen

processing system” and “a data storage device attached to or positioned within the data communications port, wherein data related to the respective filters is stored in the data storage device.” Somack is not related to and is otherwise silent regarding this structural configuration.

Instead, Somack describes *bar-coded capsules* and a *barcode on a tray* that is used to identify a capsule position. Somack (paras 9 and 60). Notably, the Office Action is silent regarding the structural configuration of a tray having a communications port as recited in claim 59 and a data storage device positioned within the data communications port, which is consistent with the deficiencies of Somack. After reviewing the figures of Somack, Applicant is not able to identify any such structure, and the Office Action has also failed to specifically identify a component in Somack that corresponds to a tray, a communications port and a data storage device so configured.

Marsh and Nova also fail to disclose, and are not related to, “a tray defining a plurality of apertures for holding respective biological specimen filters to be used for collecting portions of respective biological specimen samples to be examined and further defining a separate recess configured to mate or interface with a component of the specimen processing system.

In contrast, Marsh is directed to a docking connector for a computer. Marsh is understandably silent regarding a tray that defines apertures for specimen filters and further defines a separate recess that is configured to mate or interface with a component of a specimen processing system and, in addition, in which a data storage device is positioned and that stores data related to the respective filters is stored in the data storage device.

Nova is also deficient relative to these limitations. The cited sections of Nova fail to disclose “a tray defining a plurality of apertures for holding respective biological specimen filters to be used for collecting portions of respective biological specimen samples to be examined and further defining a separate recess (which is not an aperture for holding a specimen filter) configured to mate or interface with a component of the specimen processing system” as recited in claim 1. In contrast, the cited section of Nova describes a microplate having a memory device in, on or otherwise in contact with each of a plurality of wells. Nova (col. 14, lines 41-43). The Office Action does not specifically identify components of Nova that allegedly correspond to a tray, specimen filter, apertures defined by a tray for holding filters or a separate recess. Further, Applicant notes that Nova refers to a filter or frit in a different structural context

that is not related to the sections of Nova cited in the Office Action. *See, e.g.,* Nova (Fig. 41, “filter or frit 9720).

Further, as discussed above, the Office Action has not established that the plate assembly 50 (alleged tray) is configured to mate or interface with a component of a specimen processing system. Somack para. 10 explains that a tray may be capable of automation of robotic work stations, but is otherwise silent as to how this would be done, and the Office Action has not established that it is necessarily the case that the plate assembly (which is shown in Fig. 7 as having solid side walls) is so configured.

Thus, the cited references, individually and even if somehow properly combined, fail to disclose each limitation of claims 1 and 59, and it is respectfully submitted that these claims are patentable over the cited references. Claims 9 and 10, which depend from claim 1, and claims 60-65 and 67-69, which depend from claim 59, are also believed patentable for at least these same reasons, particularly in view of the substantial deficiencies of Somack.

Accordingly, Applicant respectfully requests that the rejection of claims 8-10 and 25-28 under 35 U.S.C. §103(a) be withdrawn.

#### **IV. Claim 13 Is Patentable Over Somack and Crosby**

Dependent claim 13 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Crosby. It is conceded that Somack fails to disclose information stored in a bar-code including the expiration date of the filter medium. Office Action (p. 5). Crosby is cited for the limited purpose of allegedly disclosing “the stored data indicating whether the respective filters have expired” as recited in claim 13. However, Crosby does not cure the above-discussed deficiencies of Somack and has its own deficiencies.

Crosby describes a strip test assay (not a tray for filter) having machine-readable information such as a bar-code 4. The strip test assay has a sample zone 1, a test zone 2 and an optional quality control zone 3. Crosby (col. 3, lines 34-35; col. 4, lines 11-21). The cited section of Crosby explains that the machine-readable information includes information of an “expiration date” but does not explain to what the expiration date relates. However, other sections of Crosby explain a strip test assay is provided with a machine-readable bar code 4. Crosby (col. 3, lines 34-35; Fig. 1). As explained by Crosby, a “bar code refers to a printed horizontal strip of vertical bars of varying widths, groups of which represent decimal digits or

other information and *are used for identification purposes.*” Crosby (col. 3, lines 35-38) (emphasis added).

Thus, the bar-coded strip is not a tray defining apertures for filters and defining a separate recess. Further, the bar-coded strip does not include a data storage device positioned within a recess. Moreover, the bar-coded strip does not have such a data storage device that stores data related to filters. This conclusion is consistent with Crosby describing use of a filter in a different context and not explaining that the bar code 4 is related to the filter. *See, e.g.*, Crosby (col. 4, lines 16-21). The Office Action is also understandably silent in this regard. MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient).

Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of independent claim 1 and dependent claim 13. Accordingly, Applicant respectfully requests that the rejection of claim 13 under 35 U.S.C. §103(a) be withdrawn.

#### **V. Claims 14-16 Are Patentable Over Somack**

Dependent claims 14-16 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack. Dependent claims 14-16 incorporate the same limitations as claim 1 and, therefore, are believed patentable over Somack in view of the above remarks. Accordingly, Applicant respectfully requests that the rejection of claims 14-16 under 35 U.S.C. §103(a) be withdrawn.

#### **VI. Claims 5, 6, 18, 19, 21-23, 29-31, 33-35 and 39-41 Are Patentable Over Somack and Nova**

Claims 5 and 6 (which depend from claim 1), independent claim 18 and claims 19, 21-23, 29-31, 33-35 and 39-41 (which depend from claim 18) stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Nova. Applicant notes that claim 43 is rejected, but claim 43 was canceled.

Applicant respectfully submits that the remarks regarding independent claim 1 render the rejection of dependent claims 5 and 6 moot.

Further, Somack is clearly deficient relative to the system recited in claim 18. As discussed above, Somack fails to disclose the structural combination of “a tray defining an aperture for holding the filter and further defining a separate recess,” “a data storage device positioned within the recess” and “a communications interface coupled to each of the data storage device and the processor, wherein data related to the filter is stored in the data storage device and can be retrieved there from by the processor through the communications interface.” Nova does not cure these deficiencies.

Dependent claims 19, 21-23, 29-31, 33-35 and 39-41 incorporate the same limitations as claim 18 and, therefore, are believed patentable over Somack and Nova in view of the above remarks.

Accordingly, Applicant respectfully requests that the rejection of claims 5, 6, 18, 19, 21-23, 29-31, 33-35 and 39-41 under 35 U.S.C. §103(a) be withdrawn.

#### **VII. Claims 26-28, 36 and 37 Are Patentable Over Somack, Nova and Marsh**

Claims 26-28, 36 and 37 (which depend directly or indirectly from independent claim 18) stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Nova and Marsh. Thus, it is believed that these claims are patentable for at least the same reasons as discussed above. Accordingly, Applicant respectfully requests that the rejection of claims 26-28, 36 and 37 under 35 U.S.C. §103(a) be withdrawn.

#### **VIII. Claim 32 Is Patentable Over Somack, Nova and Crosby**

Dependent claim 32 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Nova and further in view of Crosby. Crosby is sighted for the limited purpose of allegedly disclosing “the stored data indicating whether the filter has expired” as recited in claim 32 but the references, individually and if combined, cannot support the rejection. Deficiencies of Somack and Nova are discussed above.

Crosby describes a strip test assay (not a tray for a filter) having machine-readable information such as a bar-code 4. The cited section of Crosby explains that the machine-readable information includes information of an “expiration date” but does not explain to what the expiration date relates. Other sections of Crosby explain a strip test assay is provided with a machine-readable bar code 4. Crosby (col. 3, lines 34-35; Fig. 1). As explained by Crosby, a “bar code refers to a printed horizontal strip of vertical bars of varying widths, groups of which represent decimal digits or other information and *are used for identification purposes.*” Crosby

(col. 3, lines 35-38) (emphasis added). Thus, the bar-coded strip is not a tray defining apertures for filters and defining a separate recess. Further, the bar-coded strip does not include a data storage device positioned within a recess. Moreover, Crosby does not disclose that a bar-code indicates whether the filter has expired, which is consistent with Crosby describing use of a filter in a different context and does not explain that the bar code 4 is related to the filter. *See, e.g.*, Crosby (col. 4, lines 16-21).

Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of independent claim 18 and 32. Accordingly, Applicant respectfully requests that the rejection of claim 32 under 35 U.S.C. §103(a) be withdrawn.

#### **IX. Claims 38 and 42 Are Patentable Over Somack, Nova and McDevitt**

Dependent claims 38 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Nova and further in view of McDevitt. The deficiencies of Somack and Nova are discussed above, and McDevitt paragraph 558 is cited for the limited purpose of allegedly disclosing “the communications interface comprising a wireless interface” as recited in claim 38 and “the respective interfaces comprising electro-optical interfaces” as recited in claim 42.

However, McDevitt paragraph 558 does not cure the determinative deficiencies of Somack and Nova as discussed above. Further, independent claim 18 (from which claims 38 and 42 depend) recites that a communications interface is coupled to each of the data storage device and the processor and “wherein data related to the filter is stored in the data storage device and can be retrieved there from by the processor through the communications interface.” However, paragraph 558 of McDevitt explains that a data transfer system is used to transfer “digital chemistry/biochemistry data” as opposed to data related to the filter. In fact, paragraph 558 does not even refer to a filter. The deficiencies of paragraph 558 in this regard are also consistent with the fact that McDevitt describes a filter in a different section in a different context that is not related to digital chemistry/biochemistry data.

Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of independent claim 18 and dependent claims 38 and 42. Accordingly, Applicant respectfully requests that the rejection of claims 38 and 42 under 35 U.S.C. §103(a) be withdrawn.

**X. Claim 66 Is Patentable Over Somack, Nova and Crosby**

Dependent claims 38 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Somack in view of Nova and further in view of McDevitt. Crosby is cited for the limited purpose of allegedly disclosing “the stored data indicating whether the respective filters have expired” as recited in claim 66, but does not cure the above-discussed deficiencies of Somack and Nova and has its own deficiencies.

Thus, the cited references, individually and even if somehow properly combined, fail to disclose, teach or suggest each limitation of independent claim 18 and dependent claim 66. Accordingly, Applicant respectfully requests that the rejection of claim 66 under 35 U.S.C. §103(a) be withdrawn.

**CONCLUSION**

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

**VISTA IP LAW GROUP LLP**

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By:           /GaryDLueck/            
 Gary D. Lueck  
 Reg. No. 50,791  
 Attorneys for Applicant

Customer Number  
**41696**  
 PATENT TRADEMARK  
 OFFICE

VISTA IP LAW GROUP LLP  
 12930 Saratoga Avenue, Suite D-2  
 Saratoga, CA 95070  
 Phone (408) 777-2905  
 Fax (408) 877-1662